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In the Supreme Court of the United States

BETTY JOBLOVE, ET AL., PETITIONERS

v.

BARR LABORATORIES, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the federal antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not challenge the validity of the patent or market its own version of the drug until the expiration of the patent, in exchange for a substantial payment from the patent holder.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. The United States submits that the petition for a writ of certiorari should be denied. Although the petition presents an important and difficult question, and the court of appeals adopted an incorrect standard, this case does not appear to be a good vehicle for resolving the question presented.

STATEMENT

Respondent AstraZeneca PLC (Zeneca),[1] a pharmaceutical company, marketed tamoxifen citrate (tamoxifen), the most widely prescribed drug for the treatment of breast can-

[1] Respondents AstraZeneca Pharmaceuticals LP and Zeneca Inc. are subsidiaries of AstraZeneca PLC (or its corporate predecessor); Imperial Chemical Industries PLC (ICI) was the parent of AstraZeneca PLC's predecessor. This brief refers to respondents (and, where appropriate, ICI) collectively as Zeneca.

cer, under the brand name Nolvadex. Zeneca held a patent for the drug, United States Patent No. 4,536,516 (the '516 patent). In 1987, Zeneca sued respondent Barr Laboratories after Barr proposed to market a generic version of tamoxifen that would allegedly infringe Zeneca's patent. After the district court held Zeneca's patent invalid, Zeneca and Barr entered into a settlement providing, *inter alia*, that Zeneca would make a cash payment to Barr and that Barr would not market its generic version of the drug until after the patent expired. Petitioners, purchasers of tamoxifen and others, then filed suit against respondents under the federal antitrust laws and the laws of various States, contending that the settlement agreement unlawfully restrained competition. The district court dismissed the complaint, Pet. App. 70a-107a, and the court of appeals affirmed, *id.* at 1a-69a, 110a-135a.

1. The settlement at issue here arose against the statutory backdrop of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act or the Act), Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Act establishes procedures designed to facilitate the market entry of lower-priced generic drugs while maintaining incentives to invest in new drug development. Under the Act, a company seeking approval from the Food and Drug Administration (FDA) to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. 21 U.S.C. 355(b). Once an NDA has been approved and a company starts marketing a "brand name" version of the drug, a company seeking to market a generic version of that drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is the "bioequivalent" of its brand name counterpart. 21 U.S.C. 355(j).

If the brand name version of the drug is the subject of one or more patents, FDA may not make its approval of an ANDA effective before the expiration of any such patent, unless the applicant makes a "paragraph IV certification" that such patent is either invalid or not infringed by the generic version.

21 U.S.C. 355(j)(2)(A)(vii)(IV). If the patent holder files an action for infringement within 45 days of receiving notification of that certification, FDA's approval is automatically stayed for 30 months (unless the patent expires or a court holds the patent invalid or not infringed). *Ibid.* Under the version of the Hatch-Waxman Act in effect at the time of the relevant events, the first company to file an ANDA with a paragraph IV certification for a particular drug was granted the exclusive right to market the generic version until 180 days after the earlier of two dates: (1) when the company began commercial marketing of the generic version, or (2) when a court held the patent invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iv) (1984).[2]

2. Barr filed an ANDA to market a generic version of tamoxifen. In 1987, Barr amended its ANDA to include a paragraph IV certification; shortly thereafter, Zeneca sued Barr for patent infringement in the United States District Court for the Southern District of New York. In 1992, the district court held the '516 patent invalid and unenforceable on the ground that, in a predecessor patent application, Zeneca had fraudulently withheld data regarding the hormonal effects of tamoxifen on mice. *Imperial Chem. Indus., PLC* v. *Barr Labs.*, 795 F. Supp. 619, 621-622 (S.D.N.Y. 1992).

Zeneca appealed to the Federal Circuit. While that appeal was pending, Zeneca and Barr entered into a settlement, conditioned on vacatur of the judgment invalidating the '516 patent. The settlement provided that Barr would receive a cash payment of $21 million from Zeneca, withdraw its paragraph IV certification and its challenge to the validity of the patent, and enter into a license with Zeneca for the duration of the patent term, under which Barr would be allowed to market tamoxifen supplied by Zeneca. According to petitioners,

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[2] In 2003, Congress provided for forfeiture of the exclusivity period in various circumstances, and also provided that any generic manufacturer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself. See pp. 19-20, *infra*.

Zeneca and Barr also agreed that Barr would not market its generic version of the drug until the patent expired. If another generic manufacturer successfully invalidated the patent, the parties allegedly understood that Barr would attempt to invoke the exclusivity period on the basis of its previous paragraph IV certification (and argue that the exclusivity period would not begin to run until Barr began commercial marketing of the generic version of the drug); if it were successful, Barr would effectively discourage any other generic manufacturer from entering the market until the patent expired.[3] Pet. App. 74a-75a; C.A. App. A50-A51.

As agreed, Zeneca dismissed its appeal, and Zeneca and Barr moved to vacate the district court's decision. Consistent with its practice at the time, the Federal Circuit granted the parties' motion. *Imperial Chem. Indus., PLC* v. *Heumann Pharm. GmbH & Co.*, 991 F.2d 811 (1993) (Table).

Three other companies later filed ANDAs with paragraph IV certifications for generic versions of tamoxifen. Zeneca sued all three for patent infringement and prevailed. While that patent infringement litigation was still pending, Barr attempted to invoke the 180-day exclusivity period, but FDA (after litigation on the issue) ultimately refused to allow it to do so. Pet. App. 76a-78a.

3. On February 13, 2002, various plaintiffs (including petitioners) filed a class action against Zeneca and Barr in the United States District Court for the Eastern District of New York. C.A. App. A19-A79. In their complaint, plaintiffs alleged that the settlement unlawfully restrained competition

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[3] Zeneca and Barr entered into the settlement in 1993. In 1994, FDA published a rule providing that a company could avail itself of the exclusivity period only if it "successfully defended" against a suit for patent infringement; in 1998, FDA announced that it would no longer enforce that rule. See Center for Drug Evaluation & Research, FDA, *Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 3-4 (1998) <http://www.fda.gov/cder/guidance/2576fnl.pdf>.

by preventing Barr (and others) from marketing generic versions of the drug, thereby enabling Zeneca to continue monopolizing the market for tamoxifen. *Id.* at A36-A60. The complaint sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1 and 2, see C.A. App. A64-A67, and also sought injunctive and declaratory relief and damages under the "antitrust and/or consumer protection laws" of 21 States (and the District of Columbia) that allegedly allowed the recovery of damages by indirect purchasers, see *id.* at A69-A75.

Respondents moved to dismiss the complaint for failure to state a claim. On August 20, 2002, Zeneca's patent expired. At oral argument on respondents' motion to dismiss, respondents asserted that the expiration of the patent mooted plaintiffs' Sherman Act claims. 9/27/02 Tr. 15-16. Respondents, however, did not move to dismiss the claims on that basis.

The district court granted respondents' motion to dismiss. Pet. App. 70a-107a. With regard to plaintiffs' Sherman Act claims, the court reasoned that a patent settlement would violate the federal antitrust laws if the parties had "entered into [the settlement] in bad faith and used the agreement to restrain or monopolize trade," *id.* at 84a, but determined that plaintiffs had failed sufficiently to allege bad faith, *id.* at 91a-98a. The court held, in the alternative, that plaintiffs had failed sufficiently to allege that they had suffered antitrust injury. *Id.* at 98a-103a. With regard to plaintiffs' antitrust claims under state law, the court noted that the parties had "agree[d] that state antitrust law should be construed similarly to federal antitrust law where possible." *Id.* at 105a. The court held that dismissal of the state antitrust claims was appropriate in light of the failure of plaintiffs' Sherman Act claim, which involved "the same allegations." *Ibid.*[4]

[4] With regard to plaintiffs' other state-law claims, the district court reasoned that those claims would be preempted by federal patent law unless they were based on respondents' bad faith, Pet. App. 106a, and again determined that plaintiffs had failed sufficiently to allege bad faith, *ibid.*

4. A divided court of appeals affirmed. Pet. App. 1a-69a, 110a-135a.

a. The court of appeals first concluded that the complaint could not state an antitrust claim based on the settlement alone "without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court." Pet. App. 35a. The court reasoned that "'courts are bound to encourage' the settlement of litigation," *id.* at 29a (citation omitted), and that restrictions on patent settlements might frustrate "the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents," *id.* at 30a-31a. Although the court of appeals acknowledged that a settlement could be invalid under the antitrust laws if the parties had entered into the settlement in bad faith, the court refused to consider the likelihood of success on the underlying patent infringement claim in assessing the validity of a settlement. *Id.* at 31a-32a. The court reasoned that it was impossible to assess the likelihood of Zeneca's success on appeal "with any degree of assurance." *Id.* at 32a.

The court of appeals next concluded that the mere allegation that the patent holder made a "reverse payment" to the alleged infringer as part of the settlement also did not suffice to make out an antitrust claim. Pet. App. 35a-40a. The court reasoned that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *Id.* at 37a. The court explained that a prospective generic manufacturer "has relatively little to lose" in a patent infringement suit precipitated by a paragraph IV certification, *id.* at 38a, whereas "[t]he patent holder's risk if it loses * * * is correspondingly large," *id.* at 40a.

The court of appeals rejected plaintiffs' argument that the settlement was invalid under the antitrust laws because the *size* of the reverse payment was excessive. Pet. App. 41a-53a. The court acknowledged that "[t]here is something on the face

of it that does seem 'suspicious' about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit." *Id.* at 42a. According to the court, however, "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over * * * the patented product." *Id.* at 43a. The court explained that "the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly." *Id.* at 48a-49a.

The court of appeals ultimately held that, "absent an extension of the monopoly beyond the patent's scope * * * and absent fraud * * *, the question is whether the underlying infringement lawsuit was objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Pet. App. 52a (internal quotation marks and citation omitted). Applying that standard, the court determined that the settlement in this case was valid under the antitrust laws. *Id.* at 53a-59a.[5] The court did not separately discuss plaintiffs' state-law claims.

b. Judge Pooler dissented. Pet. App. 110a-135a. In her view, the standard of liability announced by the majority "is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." *Id.* at 117a. While she "agree[d] that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal," *id.* at 118a, she asserted that the "objective baselessness" prong of the majority's test was too narrow because it "ill serves the public interest in having the validity of patents litigated." *Id.* at 120a. Judge

[5] The court of appeals also held that plaintiffs' allegations that Barr had attempted to enforce the exclusivity period after the settlement had been reached did not independently state an antitrust claim. Pet. App. 53a-68a.

Pooler stated that she "s[aw] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context." *Id.* at 125a. "[I]n assessing the reasonability of a Hatch-Waxman settlement," she explained, "I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled," and "secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement." *Id.* at 126a. "Because plaintiffs allege[d] that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants," Judge Pooler concluded that the complaint stated a valid antitrust claim. *Ibid.*

DISCUSSION

The petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market by the alleged infringer in exchange for a "reverse payment" from the patent holder. Patents by their very nature restrict competition, and the antitrust laws must be construed in a manner that avoids burdening the enforcement of legitimate patent rights. On the other hand, a settlement involving a reverse payment may restrict competition in ways that are not justified by the patent at issue, to the detriment of consumers. The court of appeals applied an insufficiently stringent standard in scrutinizing the settlement at issue here. For the reasons stated below, however, this case does not appear to present an appropriate opportunity for this Court to establish the correct standard for distinguishing legitimate patent settlements, which further the important

goals of encouraging innovation and minimizing unnecessary litigation, from illegitimate settlements that impermissibly restrain trade in violation of the antitrust laws. The petition for a writ of certiorari should therefore be denied.

I. The Petition Raises Important And Complex Issues

Although "public policy wisely encourages settlements" of legal disputes, *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994), it does not follow that all settlements are consistent with the antitrust laws. In most circumstances, a settlement predicated on an agreement that one party will not sell a product in competition with another party, or that it will do so only pursuant to specified terms, would likely constitute an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

In the patent context, however, the settlement of a patent infringement claim will often involve restrictions on the sale of the product in question, and such a settlement is not necessarily impermissible or harmful to society. The Patent Act provides that "[e]very patent shall contain * * * a grant * * * of the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. 154(a)(1). A valid patent thus confers on the patent holder the "right to exclude others from profiting by the patented invention." *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). A patent holder can lawfully refuse to license a competitor to produce the patented article, or can grant licenses subject to exclusive territorial or other limitations. *Ibid.*; 35 U.S.C. 261, 271(d)(4); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000), cert. denied, 531 U.S. 1143 (2001). In many cases, the settlement of a patent infringement claim will not expand, and may even narrow, the permissible limitations on competition inherent in the patent. A patent holder may enter into such a settlement even if it believes that the likelihood that its patent will be held invalid

is relatively small, out of concern that it would suffer enormous consequences in the event of invalidation.

At the same time, competitive restraints adopted as part of a patent litigation settlement are subject to invalidation under the antitrust laws if the patent holder obtains "protection from competition which the patent law, unaided by restrictive agreements, does not afford." *United States* v. *Masonite Corp.*, 316 U.S. 265, 279 (1942). There may be particular reason to be concerned about the competitive consequences of a settlement that includes a substantial payment from the patent holder to the alleged infringer. Such a "reverse payment" can be a device for the sharing of the monopoly rents that are preserved when the alleged infringer is induced to stay out of the relevant market and drop its challenge to the validity of the patent. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749 (2003) (Hovenkamp); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 408 (2003).

The Hatch-Waxman Act provides particular incentives for reverse payments in the context of settlements of patent infringement claims involving pharmaceutical products. On the one hand, as the court of appeals recognized, the Act creates incentives for such payments by authorizing and encouraging patent holders to initiate infringement litigation against prospective generic manufacturers before any actual infringement has occurred. See Pet. App. 37a-40a. Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

On the other hand, when a patent holder is able to settle with the first generic competitor that files an ANDA, the patent holder may be able to manipulate the 180-day exclusivity period that the Hatch-Waxman Act grants to that competitor in order to protect its own monopoly profits. Under the version of the Act in effect at the time of the relevant events here, "[i]t [wa]s widely understood that the 180-day exclusivity period" created an incentive for the parties to "settle the litigation with a 'non-entry payment' to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Hovenkamp 1755; see 21 U.S.C. 355(j)(5)(B)(iv) (2000).

Patent litigation settlements that include reverse payments thus implicate complex and conflicting policy considerations at the intersection of patent and antitrust law, with the Hatch-Waxman Act introducing further complexity in the pharmaceutical context. On the one hand, the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a *weak* patent by dividing its monopoly profits with an alleged infringer. The risks are magnified in the pharmaceutical context, where the settling parties may be in a position to constrain competition from other generic manufacturers by invoking the provisions of the Hatch-Waxman Act. On the other hand, the public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its *valid* patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation. In the pharmaceutical context, the litigation dynamics created by the Hatch-Waxman Act may cause even a patent holder with a relatively strong claim to enter into a settlement with a reverse payment.

Those competing considerations suggest that, in the context of the Hatch-Waxman Act, the mere presence of a substantial reverse payment as part of the settlement of a patent infringement claim is not sufficient to establish that the settlement is unlawful under the Sherman Act. The correct approach is to apply the rule of reason, rather than a rule of per se legality (or illegality). Under that rule, which is "presumptively applie[d]" to claims under Section 1 of the Sherman Act, a plaintiff "must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful." *Texaco Inc.* v. *Dagher*, 126 S. Ct. 1276, 1279 (2006). In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims, viewed ex ante. See U.S. Br. at 11, *FTC* v. *Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 06-273); cf. Hovenkamp 1759 (proposing standard that incorporates alleged infringer's "ex ante likelihood of prevailing in its infringement lawsuit").

II. The Court Of Appeals Adopted An Insufficiently Stringent Standard For Scrutinizing Patent Settlements That Include Reverse Payments

The dissenting opinion below correctly suggested that a court reviewing an antitrust challenge to a settlement of a patent infringement claim that includes a reverse payment should apply the rule of reason—and that, in doing so, a court should consider "the strength of the patent as it appeared at the time at which the parties settled." Pet. App. 125a-126a. The panel majority, however, rejected that approach and instead held that such a settlement would be valid unless (1) the settlement "extend[ed] * * * the monopoly beyond the patent's scope"; (2) the settlement involved fraud; or (3) the underlying lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the

merits." *Id.* at 52a (internal quotation marks and citation omitted). That standard is erroneous.

A. The court of appeals primarily erred by focusing on whether the underlying patent infringement claim was "objectively baseless"—a standard typically used in determining whether a defendant is entitled to antitrust immunity under the *Noerr-Pennington* doctrine—rather than engaging in a broader inquiry concerning the patent holder's likelihood of success on that claim. Pet. App. 52a. The court of appeals correctly recognized that, in passing on the validity of a settlement, a reviewing court should view the settlement from the perspective of the parties at the time they entered into it. *Id.* at 32a. The court nevertheless refused to inquire into the likelihood of success on the patent infringement claim, on the ground that it was impossible to assess the likelihood of success (in this case, Zeneca's likelihood of prevailing on appeal) "with any degree of assurance." *Ibid.* A court, however, would not need to conduct a full trial on the merits of the underlying claim in assessing the patent holder's likelihood of success, nor would a court be required to establish the likelihood of success with mathematical precision as part of the overall reasonableness inquiry. Such a limited examination of the merits of the claim (aided by the analysis of any other relevant factors surrounding the parties' negotiations) is hardly impossible. Indeed, similar inquiries are commonplace, such as in deciding whether to grant a preliminary injunction, see, *e.g.*, *Ashcroft* v. *ACLU*, 542 U.S. 656, 666 (2004), or in reviewing the fairness of a proposed class-action settlement, see, *e.g.*, *Weinberger* v. *Kendrick*, 698 F.2d 61, 74 (2d Cir. 1982) (Friendly, J.) (stating that a reviewing court must form "an intelligent and objective opinion of the probabilities of ultimate success should the claim be litigated," but need not conduct a trial) (citation omitted), cert. denied, 464 U.S. 818 (1983).

The atypical facts of this case illuminate the court of appeals' error in refusing to consider the strength of the in-

fringement claim beyond a determination that the claim was not objectively baseless. At the time the parties entered into the settlement at issue here, the district court had already held Zeneca's patent invalid in a decision on the merits.[6] As the court of appeals acknowledged, the Federal Circuit "would have reviewed [the district court's] factual findings underlying [its] conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity." Pet. App. 33a (citing *Shelcore, Inc.* v. *Durham Indus., Inc.*, 745 F.2d 621, 624-625 (Fed. Cir. 1984)). Thus, this case appears to be one in which, at the time of settlement, there was reason to doubt the patent holder's likelihood of success. To be sure, the fact that Zeneca prevailed in all three of its other infringement suits presenting the identical issue might suggest that affirmance of the invalidity ruling was far from certain. The standard articulated by the court of appeals, however, precluded any such assessment.

In adopting its "objective baselessness" standard for the invalidity of patent settlements containing reverse payments, the court of appeals gave undue weight to what it viewed as the established principle that "settlement of patent litigation * * * is encouraged for a variety of reasons[,] even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents." Pet. App. 51a. While it is true that the law generally encourages settlements, the Patent Act does not embody a policy of promoting the interests of patent holders at all costs. To the contrary, while designed to provide substantial incentives for true innovation,

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[6] Because the district court's decision invalidating the '516 patent would have precluded Zeneca from enforcing its patent against other generic manufacturers, the settlement between Zeneca and Barr was conditioned on vacatur of that decision. See p. 3, *supra*. As a practical matter, settlements are now unlikely to occur under similar circumstances, because this Court subsequently held that "mootness by reason of settlement does not justify vacatur of a judgment under review." *U.S. Bancorp Mortgage Co.* v. *Bonner Mall P'ship*, 513 U.S. 18, 29 (1994).

the Patent Act also reflects the "important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Accordingly, this Court has repeatedly stressed the importance of definitively resolving the validity of patents, so that the public can remain free to use unpatented (or unpatentable) ideas. See, *e.g.*, *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993) (noting the "importance to the public at large of resolving questions of patent validity"); *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971) (describing the Court's "consistent view" that "the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted"); *Edward Katzinger Co.* v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid"). Indeed, the Hatch-Waxman Act itself promotes that interest, by creating incentives for generic manufacturers to call into question the validity of patents by means of ANDAs with paragraph IV certifications. Particularly given the "fundamental national economic policy" in favor of competition that the federal antitrust laws promote, *National Gerimedical Hosp.* v. *Blue Cross of Kansas City*, 452 U.S. 378, 388 (1981) (citation omitted), a court considering an antitrust challenge to a patent settlement should evaluate the settlement in light of the legitimacy of the patent rights at issue in the underlying litigation.

B. The court of appeals' decision in this case is arguably in some tension with the Eleventh Circuit's decision in *FTC* v. *Schering-Plough Corp.*, 402 F.3d 1056 (2005), cert. denied, 126 S. Ct. 2929 (2006). In *Schering-Plough*, the Eleventh Circuit held that the "proper analysis" of an antitrust challenge to a patent settlement "requires an examination of:

(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066 (citing *Valley Drug Co.* v. *Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004)). Although the court of appeals in this case expressed its approval of the Eleventh Circuit's focus on whether "'the exclusionary effects of the agreement' exceed the 'scope of the patent's protection,'" Pet. App. 53a (quoting *Schering-Plough*, 402 F.3d at 1076)), the Eleventh Circuit (unlike the court of appeals here) did not purport to hold that proof of "sham" or "objectively baseless" litigation is a prerequisite to antitrust liability (in the absence of proof that the settlement extended the patent holder's monopoly beyond the patent's scope). Instead, the Eleventh Circuit did not foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim in contending that the settlement was invalid. As petitioners suggest (Reply Br. 2), therefore, the Eleventh Circuit's standard might permit imposition of antitrust liability in some cases in which the standard adopted below would not.[7]

III. This Case Does Not Present A Good Vehicle For Addressing The Question Presented

Although the court of appeals applied an erroneous standard for scrutinizing patent infringement settlements that

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[7] Petitioners contend (Pet. 12-13) that the court of appeals' decision also conflicts with *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), cert. denied, 543 U.S. 939 (2004), which held that an interim settlement containing a reverse payment constituted a per se violation of the antitrust laws. As the government has previously explained, however, *Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and it is thus uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case. See U.S. Br. at 16-17, *Schering-Plough*, *supra* (No. 06-273); U.S. Br. at 11-15, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779).

include reverse payments, this case is not an attractive vehicle for the Court's consideration of the difficult and context-sensitive questions involved in assessing the legality of such settlements. The federal antitrust claims in this case appear to be moot, the factual setting is atypical and unlikely to recur, and subsequent regulatory changes may undercut one of the theories of competitive harm advanced by petitioners. For those reasons, the petition should be denied.

A. In their complaint in this case, petitioners sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1 and 2. See C.A. App. A64-A67. Specifically, petitioners sought "the issuance of an injunction prohibiting [respondents'] continued compliance with the terms of the unlawful Agreement[s]": *i.e.*, the settlement that terminated the patent infringement litigation. See *id.* at A67. Zeneca's patent, however, expired in 2002—and it is undisputed that the settlement ceased to have any effect at that time. As a result, an injunction prohibiting compliance with the settlement would have no operative force. Because petitioners did not seek any other equitable relief, the Sherman Act claims in this case appear to be moot. Nor, to the extent that respondents have entered into *other* similar settlements affecting petitioners (involving different drugs), could petitioners avail themselves of the exception to the mootness doctrine applicable where a controversy is capable of repetition yet evading review, because they cannot show that *those* settlements would expire before they could obtain relief. See, *e.g.*, *Spencer* v. *Kemna*, 523 U.S. 1, 17-18 (1998). There is nothing inherent in this context that would produce only settlements of brief duration.

Petitioners also sought relief under the "antitrust and/or consumer protection laws" of 21 States (and the District of Columbia) that allegedly allowed the recovery of damages by indirect purchasers. See C.A. App. A69-A75. It is unclear, however, whether or to what extent the disposition of those state-law claims would turn on resolution of the ques-

tion presented. The district court noted that the parties had "agree[d] that state antitrust law should be construed similarly to federal antitrust law where possible," Pet. App. 105a, and the court of appeals seemingly operated on that assumption in affirming the district court's dismissal of the entire action. Notably, however, petitioners have not identified even a single state statute (of the many on which the complaint relied) that has been construed as being coterminous in all respects with federal antitrust law. Indeed, the fact that the damages claims were pleaded only under state law is presumably reflective of one important difference between federal and state antitrust law: the extent to which state law allows suits for damages by indirect purchasers. While it presumably would be within this Court's discretion to grant certiorari here on the assumption that its resolution of the Sherman Act question would ultimately prove controlling, or at least informative, in the disposition of petitioners' state-law claims, cf. *Three Affiliated Tribes of the Ft. Berthold Reservation* v. *Wold Eng'g, P.C.*, 467 U.S. 138, 152 (1984), it would certainly be unusual, and potentially undesirable, for the Court to determine the scope of federal antitrust liability in a context in which the relevance of that determination to the state laws at issue is entirely uncertain.

To the extent that the state antitrust laws on which petitioners relied are *not* coterminous with federal antitrust law, moreover, this case would present a federal question only insofar as federal patent law would preempt petitioners' state-law claims. However, no preemption question is presented in the petition; preemption was not a focus of the court of appeals' analysis; and resolution of the Sherman Act question that *is* raised in the petition would not necessarily resolve the preemption issue. Nor has the preemption issue arisen in other court of appeals decisions addressing the question presented, let alone generated a circuit conflict. Because the importance and difficulty of the question presented arise out of the dynamic interplay between the federal patent and anti-

trust laws, rather than the relationship between federal patent law and state antitrust law, it would be preferable to consider that question in a case that actually involves live *federal* antitrust claims.

B. The settlement challenged in this case involves an unusual factual setting that will almost certainly not recur, and thus there is a risk that the Court's resolution of this case could turn on its unique facts in a way that would not provide clear guidance for other, more common factual settings. The government is not aware of any other Hatch-Waxman patent settlements arising after a district court judgment of *invalidity*, and none is likely to occur in the future in light of this Court's decision in *U.S. Bancorp Mortgage Co.* v. *Bonner Mall Partnership*, 513 U.S. 18 (1994), which should prevent a patent holder from obtaining vacatur of a judgment of invalidity by settling the case while the appeal is pending. The fact that the settlement at issue in this case occurred after a judgment of invalidity highlights the court of appeals' error in refusing to assess the validity of the patent, and might play a substantial role in the Court's analysis of the merits. A decision emphasizing that factor, however, might shed little light on the proper disposition of future cases challenging reverse-payment settlements in other factual settings.

C. Changes in the regulatory context have also altered the regulatory dynamic with respect to one of the theories of competitive harm advanced by petitioners, who argued in part below that Barr's agreement to assert its exclusivity rights could preclude competition from other generics. See Pet. App. 59a-68a. In 2003, Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons, including the withdrawal of a paragraph IV certification. See 21 U.S.C. 355(j)(5)(B)(iv) and (D) (Supp. IV 2004).[8] Congress also provided that any generic manufac-

[8] The statute also provides for forfeiture for failure to market a generic drug pursuant to an approved ANDA, but only after a final adjudication of patent

turer that filed an ANDA with a paragraph IV certification on the same day as the first filer would be treated as a first filer itself (and thus would be able to take advantage of the 180-day exclusivity period as against other, later filers). See 21 U.S.C. 355(j)(5)(B)(iv)(II)(BB) (Supp. IV 2004). As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market, as Barr attempted to do in this case. Moreover, Congress specifically authorized generic manufacturers to bring "civil action[s] to obtain patent certainty" in the Hatch-Waxman context, 21 U.S.C. 355(j)(5)(C) (Supp. IV 2004), and this Court's recent decision in *MedImmune, Inc.* v. *Genentech, Inc.*, 127 S. Ct. 764 (2007), removed at least some procedural obstacles to such suits. See *Teva Pharm. USA, Inc.* v. *Novartis Pharm. Corp.*, 482 F.3d 1330, 1336-1341 (Fed. Cir. 2007). No court of appeals has addressed, in the post-2003 regulatory context, a patent settlement challenged on the ground that it will bar other generic entrants by virtue of the settling generic's exclusivity rights. To the extent the Court is inclined to address the validity of that type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime.[9]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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rights, or a settlement that includes a finding of invalidity or noninfringement. 21 U.S.C. 355(j)(5)(D)(I)(bb) (Supp. IV 2004).

[9] In addition, Congress is currently considering legislation that would prohibit "reverse payments" in settlements with ANDA filers altogether. See S. 316, 110th Cong., 1st Sess. § 3 (2007); H.R. 1902, 110th Cong., 1st Sess. § 2 (2007).

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